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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/529,053	04/06/00	WILLIAMS J	29666/35415

HM22/1019
MARSHALL O TOOLE GERSTEIN
MURRAY & BORUN
6300 SEARS TOWER
233 SOUTH WACKER DRIVE
CHICAGO IL 60606-6402

EXAMINER	
WANG, S	
ART UNIT	PAPER NUMBER
1617	6

DATE MAILED: 10/19/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

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09/529,053	04/06/00	WILLIAMS J	29666/35415

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Office Action Summary	Application N .	Applicant(s)	
	09/529,053	WILLIAMS ET AL.	
	Examin r	Art Unit	
	Shengjun Wang	1617	

-- The MAILING DATE of this communicati n appears on the cover sh et with the c rrespondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 August 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Applicant's election with traverse of invention group I in Paper No. 5 submitted August 2, 2001 is acknowledged. The traversal is on the ground(s) that the inventions have single general concept. This is not found persuasive because the other two inventions involve other technical features as discussed in the prior office action.

The requirement is still deemed proper and is therefore made FINAL.

Claim Objections

2. Claim 6 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 6 has larger scope than claim 5 regarding the viral species.

Claim Rejections 35 U.S.C. 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 8 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Claim 8 and 9 recites the limitation "another antiviral agent" or “pyrimidin” . There is insufficient antecedent basis for this limitation in the claim. It is suggested to employ phrase such as “ the method of claim 1 further comprises step …”.

Claim Rejections 35 U.S.C. 102

6. Claims 1-2, 4, 6-7 and 12 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Weithmann et al. (US Patent 5,556,870).

7. Weithmann et al. teach a method of treating viral infection, including hepatitis, comprising administering leflunomide to the patient. See, particularly, the abstract and the claim. The dosage may range from 3-50 mg daily, but may be higher if required. See, particularly, column 3, lines 7-16. Weithmann also teaches that the

Claim Rejections 35 U.S.C. 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 1-2, 4-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weithmann et al. (US Patent 5,556,870) in view of Flamand et al. (CAPLUS Abstract, AN 1991:581163), Hammer (AIDS 1996, vol. 10, suppl 3, s1-s11).

10. Weithmann et al. teach a method of treating disorder in which interleukin 1 beta is involved. The disorders includes viral infections, such as HIV or hepatitis, comprising administering leflunomide to the patient. See, particularly, the abstract and the claim. The dosage may range from 3-50 mg daily, but may be higher if required. See, particularly, column 3, lines 7-16.

11. Weithmann et al. does not teach expressly the employment of the method for treating herpes or employment of a combination with other antiviral agents.

12. However, Flamand et al. teaches that herpes infection is involved with interleukin 1 beta. See the abstract. Hammer teaches that serval pyrimidin compounds are known antiviral agents. See, particularly, page s3.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to employ the method of Weithmann for treating herpes infections, or employ a combination of leflunomide compounds with other antiviral agents such as those known pyrimidin compounds.

A person of ordinary skill in the art would have been motivated to employ the method of Weithmann for treating herpes infections, or employ a combination of leflunomide compounds with other antiviral agents such as those known pyrimidin compounds because herpes infection is known to be involved interleukin 1 beta. Also, it is prima facie obvious to combine two compositions each of which is taught in the prior art to be useful for same purpose in order to form third composition that is to be used for very the same purpose; idea of combining them flows logically from their having been individually taught in prior art; thus , the claimed invention which employ a combination of two known anti-viral agents sets forth prima facie obvious subject matter. See In re Kerkhoven, 205 USPQ 1069. Further, combination therapies for viral infection are known to be better than single agent therapy. See, Hammer, page s2, the paragraph of combination therapy. A method known to be useful for treating viral infection would have been reasonably expected to be useful for prophylactic purpose. Further, a known anti-viral agents would have been reasonably expected to be effective in vitro against virus. Finally, since leflunomide is effective against virus through different mechanism, it would have

been reasonably expected to effective against those virus with resistance to antiviral agent that inhibit viral DNA replication.

13. Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Coghlan et al. (WO 94/24095) in view of McChesney et al. (Transplantation, Vol. 57, no. 12, page 1717-1722).

14. Coghlan et al. teaches compounds with structures and biological activity closely related to leflunomide or its active metabolite. See, particularly, the abstract, page 2, the examples and the claims. These compounds are known to be useful for treating or preventing viral infection such as hepatitis and cytomegalovirus infection. See, page 4, lines 23-32.

15. Coghlan et al.. does not teach expressly the employment leflunomide or its metabolite, or the particular amount herein for administration.

16. However, McChesney et al. teaches that both leflunomide and A771726 are known to be effective in preventing viral infection. See, particularly, the abstract at page 1717, and the materials and method at page 1717-1718.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to employ the compounds taught by Coghlan et al., including both leflunomide and A771726, for treating or prevention viral infections such as hepatitis and CMV.

A person of ordinary skill in the art would have been motivated to employ the compounds taught by Coghlan et al., including both leflunomide and A771726, for treating or prevention viral infections such as hepatitis and CMV because these compounds are known to be useful for treating or preventing viral infection, and both leflunomide and A771726 are known to

be similarly useful as the other compounds. Further, a known anti-viral agents would have been reasonably expected to be effective in vitro against virus. Finally, since leflunomide is effective against virus through different mechanism, it would have been reasonably expected to effective against those virus with resistance to antiviral agent that inhibit viral DNA replication.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang, Ph.D. whose telephone number is (703) 308-4554. The examiner can normally be reached on Monday-Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

RUSSELL TRAVERS
PRIMARY EXAMINER
GROUP 1200

Shengjun Wang

AU 1617

October 12, 2001